



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,660	06/27/2003	Karla Weaver	10123/00201	6994

7590 12/04/2006
Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/608,660
Filing Date: June 27, 2003
Appellant(s): WEAVER ET AL.

MAILED
DEC 04 2006
GROUP 3700

Oleg F. Kaplun
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 31 August 2006 appealing from the Office action mailed 7 March 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Art Unit: 3761

3,621,557	Cushman	11-1971
5,810,789	Powers et al	09-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 8, 15, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,991,745 to Brown.

In the specification and figures, Brown discloses the apparatus as claimed by Appellant. In particular, Brown discloses a bidirectional fluid control valve. The valve 1 is constructed of a flat disc-shaped pad made of a flexible plastic such as silicone (see column 5, lines 35-45, column 6, lines 14-15, FIGS 3-5). The disc comprises a slit 8 that creates mating slit edges or flaps 47 and 48 that closely abut one another when in the closed position (see column 6, lines 6, lines 24-37). The valve further comprises generally square-shaped discrete ribs 7 that surround the linear slit and selectively stiffen the center valve area to control the flexure thereof, acting as a biasing member (see column 6, lines 37-63).

With regard to Appellant's recitation of the opening and closing of the valve at particular pressures, such limitations are held by the Examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner

Art Unit: 3761

in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

See MPEP § 2114.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,991,745 to Brown, as applied above.

In the specification and figures, Brown discloses the apparatus substantially as claimed by Appellant with the exception of the threshold pressure of the valve. Brown specifically discloses that the physical characteristics of the valve may be varied in accordance with the desired threshold pressure (see column 6, lines 64-67, column 7, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the valve to respond to a desired threshold pressure as claimed by Appellant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,991,745 to Brown, as applied above, in view of US 6,621,557 to Cushman et al.

In the specification and figures, Brown discloses the apparatus substantially as claimed by Appellant with the exception of a biasing member comprising a wire. Cushman

Art Unit: 3761

discloses a disk-shaped resilient slit valve with wire 46 and shoulder end of the bore 38 holding the valve in place and restraining the resilient material in a closed position.

Therefore, it would have been ordinary to one having ordinary skill in the art at the time of invention to use a wire as a biasing member around the slit of the valve disclosed by Brown in order to restrain the resilient material, maintaining a closed valve, as taught by Cushman.

Claims 9-12, 16, 18, 22-27, 30, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,810,789 to Powers in view of US 4,991,745 to Brown. In the specification and figures, Powers discloses the apparatus substantially as claimed by Appellant. In particular, Powers discloses a dual-lumen catheter with slit valves associated with each lumen of the catheter, thereby providing separate valving and fluid flow operation for each lumen (see column 5, lines 27-31). Providing additional flexible members, moveable elements, and biasing members is simply duplicating the single-lumen valve in the Brown device. Powers further discloses that the catheter system is implanted in a patient and allows external access to the fluid flowing through the catheter (see columns 5-6).

Powers fails to disclose that the valve is disc-shaped and comprises a biasing member that maintains the valve in a closed position. Brown discloses a disc-shaped slit valve with generally square-shaped discrete ribs 7 that surround the linear slit and selectively stiffen the center valve area to control the flexure thereof, acting as a biasing member (see Brown column 6, lines 37-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the biasing

Art Unit: 3761

member disclosed by Brown to the catheter slit valve disclosed by Powers in order to control the flexure of the flat disc-shaped valve, as taught by Brown.

With regard to claim 11, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. See MPEP § 2106. Furthermore, the catheter system disclosed by Powers is capable of dispensing or withdrawing fluid to and from the patient, and is capable of performing as claimed by Appellant.

With regard to Appellant's recitation of the opening and closing of the valve at particular pressures, such limitations are held by the Examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

With regard to Appellant's claims 22-27 drawn to the number and arrangement of the biasing members and slits, such variations on the prior art are considered to be obvious to one of ordinary skill in the art. It has been held that mere duplication or rearrangement of the essential working parts of a device involves only routine skill in the art. See MPEP § 2144.04.

With regard to claims 30 and 32, Brown specifically discloses that the physical characteristics of the valve may be varied in accordance with the desired threshold pressure (see column 6, lines 64-67, column 7, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the

Art Unit: 3761

valve to respond to a desired threshold pressure as claimed by Appellant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

Claims 19-21 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,810,789 to Powers in view of US 4,991,745 to Brown, as applied above, in view of US 6,621,557 to Cushman et al.

In the specification and figures, Powers and Brown disclose the apparatus substantially as claimed by Appellant with the exception of a biasing member comprising a wire. Cushman discloses a disk-shaped resilient slit valve with wire 46 and shoulder end of the bore 38 holding the valve in place and restraining the resilient material in a closed position.

Therefore, it would have been ordinary to one having ordinary skill in the art at the time of invention to use a wire as a biasing member around the slit of the valve disclosed by Brown in order to restrain the resilient material, maintaining a closed valve, as taught by Cushman.

(10) Response to Argument

Appellant argues that the ribs disclosed by Brown are formed integrally with and from the same material as the rest of the valve and do not comprise biasing members coupled to the first flexible member, or valve, as claimed by Appellant. However, Appellant's recitation that the biasing member is "coupled to" the flexible portions of the

Art Unit: 3761

valve does **not** exclude members that are formed together as one piece. Appellant argues that the flexible members of the valve and the biasing member are discrete and separate elements that are put together. However, Appellant's claim language reciting that the elements are "coupled" to one another does not necessarily mean that the elements are discrete. Giving the claim the broadest reasonable interpretation, "couple" is defined by Merriam-Webster's Collegiate Dictionary (10th Ed, 2001), as something that joins or links two things together. While Brown discloses that the ribs are integral with the valve, he discloses them as separate elements. Even when formed integrally, the ribs are coupled to the valve by the chemical bonds that join polymer chains together to form an object such as the valve with ribs disclosed by Brown. As such, Brown's disclosure of a valve with flexible flaps 47, 48 with ribs 7 that stiffen the valve flaps meet the limitations of Appellant's claim drawn to a biasing member "coupled to" the flexible member of a valve.

Appellant further argues that the ribs 7 disclosed by Brown do not constitute biasing members, since the integrally formed ribs create an opening pressure that is a property of the valve itself. However, Appellant has not sufficiently claimed two separate elements: the valve and the biasing members. Brown specifically discloses that the ribs surround the linear slit between the flaps and **selectively stiffen** the center valve area to control the flexure thereof, therefore acting as a biasing member (see column 6, lines 37-63). Such a disclosure indicates that if the Brown valve were formed without the ribs, the valve would have a particular opening pressure, and the ribs provide a biasing force that stiffens the center of the valve. Therefore, the ribs, whether or not they are formed

integrally with the valve, do, in fact, function as biasing members, since the ribs stiffen the valve. Since the ribs disclosed by Brown stiffen the flaps of the valve, they act as the biasing members claimed by Appellant, meeting the limitations of the claim.

Appellant further argues that the opening pressures disclosed by Brown are not obvious variations of the opening pressures claimed by Appellant. However, Brown specifically discloses that the physical characteristics of the valve may be varied in accordance with the desired threshold pressure (see column 6, lines 64-67, column 7, lines 1-10). It has been held that discovering the optimum value or range of values of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, Brown discloses that the threshold pressures are a result-effective variable based on the physical properties of the valve. Therefore, it would have been obvious to one having ordinary skill in the art to vary the physical characteristics of the valve disclosed by Brown to arrive at the threshold pressures claimed by Appellant.

Appellant argues that the combination of Brown and Cushman do not disclose a wire biasing element. However, Cushman specifically discloses that the wire spring 46 is deployed in a groove 14 of bore 38. The spring and the bore serve to bias the valve disc 66 in the proper position (see column 3, lines 13-47). The bore (with spring insert) further serves to restrain valve disc 66 (see column 4, lines 19-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the biasing member or rib disclosed by Brown of a metal or wire as disclosed by Cushman, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of

Art Unit: 3761

obvious design choice. In the instant case, it would have been obvious to use a metal rib as a biasing means in the Brown valve, since Cushman teaches that the metal spring and metal bore 38 cooperate to restrain valve 66 in a particular position.

With regard to Appellant's arguments drawn to the action of the biasing members "for biasing the first and second flaps toward the closed position," examiner considers such a limitation to be a statement of the intended use of the device, since it attempts to claim the action of the biasing members. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP2114. In the instant case, the combination of Brown and Cushman meet the structural limitations claimed by Appellant, and the ribs are capable of acting on the flexure of the valve flaps, meeting the limitations of the claims.

With regard to the rejection of the claims over the combination of Powers and Brown, Appellant argues that neither reference teaches a first biasing member coupled to the first flexible member. However, Appellant's recitation that the biasing member is "coupled to" the flexible portions of the valve does **not** exclude members that are formed together as one piece. Appellant argues that the flexible members of the valve and the biasing member are discrete and separate elements that are put together. However, Appellant's claim language reciting that the elements are "coupled" to one another does not necessarily mean that the elements are discrete. Giving the claim the broadest reasonable interpretation, "couple" is defined by Merriam-Webster's Collegiate Dictionary (10th Ed, 2001), as something that joins or links two things together. While

Art Unit: 3761

Brown discloses that the ribs are integral with the valve, he discloses them as separate elements. Even when formed integrally, the ribs are coupled to the valve by the chemical bonds that join polymer chains together to form an object such as the valve with ribs disclosed by Brown. As such, Brown's disclosure of a valve with flexible flaps 47, 48 with ribs 7 that stiffen the valve flaps meet the limitations of Appellant's claim drawn to a biasing member "coupled to" the flexible member of a valve.

Appellant argues that Brown is not related to medical devices and is improperly combined with Powers. However, both Brown and Powers are directed to managing fluid flow through a valve, therefore solving the common problem of flow control. Therefore, the devices are directed to a common field of endeavour, and are properly combined.

Appellant further argues that the combination of Powers, Brown, and Cushman do not disclose a "biasing member coupled the the valve." However, examiner argues that the Brown disclosure, as pointed out above, does in fact teach such a combination of a valve and a biasing member, meeting the limitations of the claims.

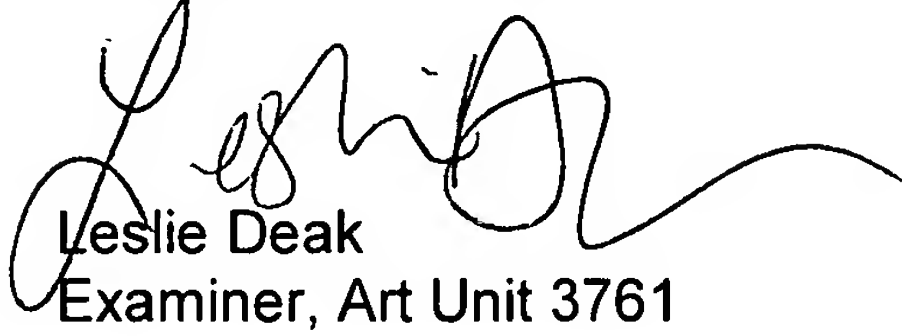
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Art Unit: 3761

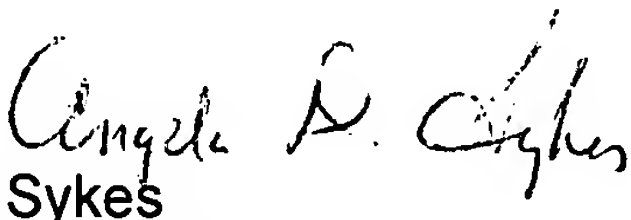
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Leslie Deak
Examiner, Art Unit 3761

Conferees:



Angela Sykes
Supervisor, TC 3700

Tatyana Zalukaeve
Supervisor, TC 3700

